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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,640	03/01/2004	Michael D. West	75802.026014	9766

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HUNTON & WILLIAMS LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
1900 K STREET, N.W.  
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WASHINGTON, DC 20006-1109

EXAMINER
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BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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01/10/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/790,640	<b>Applicant(s)</b> WEST ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/24/10.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-12,14-16,21-25,27-36 and 106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-12,14-16,21-25,27-36 and 106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/24/2010 has been entered.

The instant application is a continuation of USSN 09/527,026, now abandoned.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-8,10-12,14-16,21-24,29-36 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 87-92,94-117 of copending Application No. 11/079,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims of '930 are not specifically drawn to mammals, the instant claimed methods utilizing reprogramming of somatic cell nuclei by nuclear transfer

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were notably used in mammalian species. Thus, the generic claimed “cell” in ‘930 renders obvious the instant claimed mammalian cell..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant previously requested that this rejection be held in abeyance until otherwise allowable subject matter is identified, at which time, the filing of a TD will be considered.

### **Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) Claims 1,3-4,6-8,11-12,14-16,21-25,27-36 and 106 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method using fibroblast donor cells, does not reasonably provide enablement for the claimed method using any donor cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method of nuclear transfer using a near senescent or senescent donor cell of any type to form a blastocyst, isolation of a whole or part of the developing blastocyst, formation of a teratoma with said blastocyst whole or part, and isolation of a cell from the teratoma to obtain a cell with increased remaining populations compared to the donor.

The claims were previously deemed enabled for use of fetal fibroblasts as a donor cell. The enabled scope has been expanded to include any fibroblast cell, including fetal or adult fibroblasts as fibroblasts have an increased lifespan over other adult cells and their use in the instant invention is

exemplified in Example 3, which demonstrates adult dermal fibroblasts have an increased lifespan in culture.

The specification teaches carrying out the claimed method using a fetal fibroblast wherein the resulting cell has increased telomere length. The increased telomere length was an unexpected and novel finding as the earlier Dolly cloning using mammary epithelial cells was found to result in cell with shortened telomeres. Post-filing, Lanza reported the lengthening of telomeres in cells resulting from nuclear transfer in **Science** (2000, 288:665-669). Lanza explains that the apparent discrepancy in the length of the telomeres in cloned cells may be due to cell type used (see page 668, col. 3). Denning (2001, of record) teaches primary cells have limited proliferation capacity (Denning, page 222, col. 1, lines 5-8). In a study of sheep and goat primary somatic cells, Denning found that of primary somatic cells, fibroblasts were the only cells that either grew at all from the primary cell source or has sufficient population doublings for the selection required in targeted gene transfer. Sheep primary cell cultures primarily were composed of fibroblasts after the third passage or about 12 doublings (Denning, page 224, col. 2, lines 11-13). In a similar analysis of pig primary cultures, fibroblasts, as in the sheep study, became the predominant cell-type after three passages (Denning, page 224, col. 2, parag. 4 line 4 to page 225, col. 1, line 8).

With respect to claims 7,14,21-25,27-36 and 106, Applicant argues that there are methods of genetically modifying cells that require fewer population doublings. However, the fact remains that the only cell type taken to near-senescence prior to effective nuclear transfer is a fibroblast. The claims require the cell is senescent or near senescent.

Applicant cites art showing lengthening of telomeres of cells resulting from NT using various donor cell types. However, the donors were not senescent or near senescent as claimed. To date, the only cell type shown to recover telomere length after so many population doublings in culture are fibroblasts. The art has demonstrated that when cells are maintained in culture for many population doublings, i.e.

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senescent or near senescent, they are not effective in nuclear transfer. This is shown by the art of record where attempts to genetically manipulate cells other than fibroblasts prior to nuclear transfer have failed. The only cells effective in nuclear transfer that show increased telomere length after doubling in culture to near senescence are fibroblasts.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/

Primary Examiner, Art Unit 1632